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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,973	11/26/2003	Kelly Ann Mohr	144761	9045

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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,973	MOHR ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-11,13-17 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-11,13-17 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed January 5, 2009 have been fully considered but they are not persuasive.

The Applicant argues that none of the prior art references on record teaches or suggest calculating an axis of inertia of a segmented left cavity volume image. Specifically, the claim limitation states, "segmenting a left cavity volume image of the heart from the multi-phase axial cardiac dataset; calculating an axis of inertia of the segmented left cavity volume image."

Figure 5 of Devito illustrates a method in which the long axis is determined automatically. "Initially, the computer 8 is used to identify a region of interest in which the whole heart is contained... Only projection data between these top and bottom limits (between the whole heart) are used to reconstruct a set of transverse slices of the left ventricle." Therefore, the Examiner interprets this as a segmented portion of the original image used to reconstruct a set of transverse slices. Therefore, the reconstruction of a set of slices constituting a volume image of the left ventricle, Which would include the cavity of the left ventricle. Next, the claim requires "calculating an axis of inertia of the segmented left cavity volume image." Devito states, "From this set of transverse slices of the left ventricle, a representative slice is automatically selected using the computer." From this representative slice, a centerline is determined wherein the centerline is an estimate of the long axis not only for that single slice, but for the entire set of transverse

slices, which constitute the volume of the left ventricle. The cited portions of Devito can be found at column 4, line 36 through column 5, line 6.

Regarding the Applicant's argument on page 13 that Sheehan fails to teach or suggest "automatically generating, based on the calculated axis of inertia, at least one of a long axis orientation image and a short axis orientation image of the heart," the Examiner respectfully disagrees. Figure 3 illustrates a representation of a long axis view while Figure 5 illustrates a short axis view of the heart. Furthermore, "By dynamically viewing different cross sections of the left ventricle from different points of view, a medical practitioner can monitor dynamic changes in cardiac function with respect to wall thickness and range of motion of the cardiac wall (column 10, lines 58-62 & page 6 of the previous Office Action). To accomplish this procedure in real time, for example, during surgery, the step of manually tracing the images of the heart produced by scanning with imaging device 42 must be done automatically by CPU 32." These views are standard and it would be obvious to one of skill in the art to use these views in monitoring such dynamic changes.

For at least the reasons above, the rejection of the claims as specified in the Office Action dated October 10, 2008 still stands and is repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-8, 10-11, 13-17, 19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanebako et al. (US Patent No. 5,680,471) in view of Devito et al. (US Patent No. 5,421,331). Kanebako discloses an image processor that acquires an image including a desired portion of an object to be examined. An image memory temporarily stores the acquired image, and an outline is extracted from an area of interest from the desired portion of the object (*see* Abstract). Kanebako contemplates X-ray imaging being the image processing method, wherein a left ventricle outline extraction method is available (column 1, lines 15-32). However, other imaging modalities may be used for such methods, as described at column 8, lines 60-67. In one embodiment, a profile synthesizing section selects an image at the end of diastole from the image memory. The operator then selects, thereby verifying, the image while watching images displayed on an image display section. Subsequently, the

profile synthesizing section loads an end diastole image one frame ahead of the selected image into the second image memory. Processing is then performed on these images as further described in column 20, lines 54-67 and into column 21. The image processor of Kanebako teaches thresholding and outline, or edge detection. This process is repeated when more profiles exist, thereby growing the region. Column 11, line 65 through column 12, line 22 teaches that the thresholding technique is used to determine an outline point. Furthermore, the threshold value is able to be arbitrarily changed by the user, thereby providing ability to edit the volumes (column 11, lines 4-10). Also, the ejection fraction can be measured based on the diastolic and systolic volumes (column 9, lines 58-66). However, as can be seen in Figure 2, before this selection process can take place the long axis must be set and a long axis perpendicular profile must be generated. Kanebako does not describe automatic determination of the long axis. Devito teaches a method for automatically identifying the long axis of the left ventricle. A first estimate of the long axis is created and is then fine tuned through the process described at column 4, line 48 through column 6, line 22. While never explicitly stating that Devito is determining the axis of inertia, as defined in the specification of the current application the axis of inertia is a first estimate of the long axis. Therefore, Devito teaches this limitation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an automated long axis detection process into the system and methods of Kanebako to increase the utility of such a device and allow better results during cardiac studies (column 1, lines 44-46 of Devito).

It is noted that the portion of Kanebako where the selection of the end diastole is mentioned is only described by Kanebako as an example and is entirely capable, and intended to, acquire other phases of the heart cycle, including the end systole. This is suggested at column 9, line 61 through column 10, line 3, where Kanebako states that ejection fraction and cardiac wall motion analysis are obtained on the basis of the outline shapes determined at *both* the end diastole and end systole phases.

Regarding claim 22 as claiming the determination of all of end diastolic volume, end systolic volume, ejection fraction, stroke volume and cardiac output, the Examiner notes that these are all inter-related and can be evaluated as long as end diastolic and end systolic volumes are known through various well-known calculations. Therefore, it would be obvious to one of skill in the art to determine any and all of these as long as the end diastolic and end systolic volumes are known. Kanebako teaches, "For example, function analysis of the left ventricle includes ejection fraction measurement of obtaining the ejection fraction of the heart on the basis of the volume of the ventricle at the end of diastole and the volume of the ventricle at the end of systole which are calculated from outline data (column 9, lines 61-65)."

Claims 1 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al. (US Patent No. 5,435,310) in view of Devito et al. Sheehan discloses a method for imaging and three-dimensional modeling portions of the heart, in particularly, the left ventricular endocardial and epicardial surfaces, using image data.

Images are acquired via ultrasound or magnetic resonance and provide multiple plane imaging data at end systole and end diastole during a cardiac cycle (*see* Abstract). A magnetic resonance system provides image data for at least eight planes that are transverse to the longitudinal axis, i.e., parallel to the transverse axis of the left ventricle (column 6, lines 61-68). Also see column 11, lines 614-68. Both manual and automatic edge detection is contemplated at column 7, lines 20-33 and lines 58-61, respectively. During at least one cardiac cycle, an end diastole and an end systole will be selected for each of the image planes. In order to determine which image planes are scanned at a particular time during the cardiac cycle, an ECG will be recorded during the imaging process (column 7, lines 42-48). Once an image along one of the planes scanned is visually represented on the display, the user may use various inputs to create, or edit, the contour. Based on this information, the volume and ejection fraction may later be determined as described in Figure 16. By dynamically viewing different cross sections of the left ventricle from different points of view, a medical practitioner can monitor dynamic changes in cardiac function with respect to wall thickness and range of motion of the cardiac wall (column 10, lines 58-62 of Sheehan). However, other cardiac studies, such as perfusion studies, reference the position of the tissue region to the long axis of the left ventricle. Such a reference is inherently subjective because identification of the long axis of the patient's left ventricle requires a technician to use judgment (column 1, lines 36-42 of Devito). Devito teaches a method for automatically identifying the long axis of the left ventricle. A first estimate of the long axis is created and is then fine tuned through the process described at column 4, line 48 through column 6, line 22.

While never explicitly stating that Devito is determining the axis of inertia, as defined in the specification of the current application the axis of inertia is a first estimate of the long axis. Therefore, Devito teaches this limitation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an automated long axis detection process into the system and methods of Sheehan to increase the utility of such a device and to allow better results during cardiac studies (column 1, lines 44-46 of Devito).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

JMK